

**REMARKS**

**I. Amendments to the Claims**

Claims 1, 2, 4, 11, 13, 14, 22, 24, and 26 are all the claims pending in the application. After entry of this amendment, claims 1, 2, 4, 11, 13, 14, 22, 24, and 26-30 will be all the claims pending in the application.

Claims 1 and 11 have been amended to delete the genera *Penicillium*, *Rhizomucor*, and *Corynebacterium*.

Claims 24 and 26 have been amended to delete the species *Penicillium rugolusum*, *Penicillium lilacinum*, *Penicillium decumbence*, *Penicillium multicolor*, *Rhizopus oryzae*, *Rhizomucor pusillus*, *Rhizomucor miehei*, *Talaromyces emersonii*, *Mortierella vinacea*, *Cryptococcus albidus*, *Microbacterium arborescens*, *Corynebacterium ammoniagenes*, *Corynebacterium glutamicum*, and *Actinoplanes missouriensis*.

Claims 1, 11, 24, and 26 have been further amended to recite polypeptides having “a molecular weight of 47 kDa” rather than “an approximate molecular weight of about 47 kDa.”

New claims 27-30 recite *Aspergillis* diglycosidase defined by the process of making it. Support for these claims can be found at pages 45-47 of the specification.

## **II. Information Disclosure Statements**

### ***A. IDS filed May 11, 2005***

The Examiner has not yet initialed and returned copies of the PTO/SB/08 Form that was submitted with the Information Disclosure Statement filed on May 11, 2005.

Accordingly, Applicants include herewith a copy of the PTO/SB/08 Form which accompanied the IDS filed May 11, 2005, and respectfully request the Examiner to sign and initial the form thereby indicating that all references have been considered.

### ***B. IDS filed March 8, 2005***

The Examiner has initialed and returned copies of the PTO/SB/08 Form that was submitted with the Information Disclosure Statement (IDS) filed on March 8, 2005. However, Hoesel et al., cited in the IDS filed March 8, 2005, was not considered by the Examiner.

At page 3, paragraph 2 of the Office Action, the Examiner stated that Hoesel et al. was not considered because the reference is in a foreign language, and a Statement of Relevance was not provided.

In response, Applicants note that Hoesel et al. was cited in the International Search Report (ISR) from the International Bureau in a counterpart application citing that document. A copy of the ISR (in English) was filed with the Information Disclosure Statement submitted March 18, 2005, and the ISR indicated the relevance of the foreign document.

As stated in MPEP §609(III)(A)(3):

Where the information listed is not in the English language, but was cited in a search report or other action by a foreign patent office in a counterpart foreign application, the requirement for a concise explanation of relevance can be satisfied by submitting an English-language version of the search report or action which indicates the degree of relevance found by the foreign office. This may be an explanation of which portion of the reference is particularly relevant, to which claims it applies, or merely an "X", "Y", or "A" indication on a search report.

Thus, Applicants respectfully submit that the submission of the ISR fulfilled the requirements for the submission of a concise explanation of the foreign document, and the Examiner must initial the citation on the list of references to indicate that the article has been considered.

Accordingly, Applicants include herewith a copy of the PTO/SB/08 Form which accompanied the IDS filed March 8, 2005, and respectfully request the Examiner to return an initialed and signed copy of the list of references, indicating consideration of Hoesel et al.

## **II. Specification/Informalities**

At page 3, paragraph 12 of the Office Action, the Examiner noted that a substitute paper copy of the Sequence Listing was filed in the instant application on July 18, 2001. The Examiner further asserted that he could not find the required statement directing entry of this substitute paper copy of the Sequence Listing into the specification.

In response, Applicants have provided herewith a Supplemental Statement to Support Filing and Submission in Accordance with 37 C.F.R. § 1.821-1.825 including such a statement.

### **III. Claim Rejections Under 35 U.S.C. § 112, Second Paragraph - Indefiniteness**

At page 3, paragraph 14 of the Office Action, claims 1-2, 11, 13, 14, 24, and 26 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Specifically, the Examiner contended that the claims are indefinite in the recitation of “naturally-occurring polypeptide.” The Examiner further stated that because the physical and/or chemical characteristics that distinguish a polypeptide that is “naturally-occurring” from a non-naturally-occurring polypeptide are unclear, a person of ordinary skill in the art would not be able to determine whether a polypeptide, which otherwise satisfies all of the recited limitations of the claims, is “naturally-occurring” or non-naturally-occurring.

Applicants submit that the term “naturally occurring” is definite within the meaning of 35 U.S.C. § 112, second paragraph, based upon the plain and ordinary meaning of the term consistent with the specification and consistent with the interpretation given by those of ordinary skill in the art. Specifically, a person of ordinary skill in the art would recognize that “naturally-occurring” polypeptides are wild-type polypeptides found naturally in the recited microorganisms, and do not encompass non-naturally occurring proteins, such as endogenously expressed mutants generated by UV and/or chemical mutagenesis, or recombinantly expressed variants. See e.g., *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1327-1329, (Fed. Cir. 2003), where the term “non-naturally occurring” was given its ordinary and plain meaning as simply meaning not found in nature compared to “isolates from natural sources” or “natural isolates.”

Thus, Applicants respectfully request reconsideration and withdrawal of this rejection.

#### **IV. Claim Rejections Under 35 USC § 112, First Paragraph - Written Description**

At pages 4-7, paragraphs 16 and 17 of the Office Action, claims 1-2, 11, 13-14, 24, and 26 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

At paragraph 16, the Examiner asserted that the specification does not describe diglycosidases having the pH, stability, and MW characteristics recited in the claims.

First, the Examiner stated that while the specification describes SEQ ID NO:8 from *A. fumigatus* having an enzymatic activity at pH 2.5 to 3.0 (citing p. 47, line 25 to page 48, line 1), it does not support polypeptides from microorganisms other than *A. fumigatus* having enzymatic activity within this pH range. Second, the Examiner stated that while the specification describes diglycosidase isolated from the microorganisms listed in Table 6 at p. 45 having activity that is stable at 50°C or less, it does not support a diglycosidase from microorganisms not listed in Table 6 having that stability. Third, the Examiner stated that while the specification supports an enzyme of SEQ ID NO:8 having a molecular weight of 47 kDa (citing p. 47, lines 8-10), it does not support either a limitation of an enzyme having “an approximate molecular weight of about 47 kDa,” or diglycosidase polypeptides from microorganisms other than *A. fumigatus* having a molecular weight of 47 kDa.

Applicants note that claims 1 and 11 have been amended to recite enzymes from microorganisms of the biological genus *Aspergillus*. Claims 24 and 26 have been amended to

recite enzymes of the biological species *Aspergillus oryzae*, *Aspergillus niger*, *Aspergillus aculeatus*, and *Aspergillus fumigatus*. Applicants submit that the claimed invention is adequately described in the specification.

First, diglycosidase enzymes from *Aspergillus oryzae*, *Aspergillus niger*, *Aspergillus aculeatus*, and *Aspergillus fumigatus* have been isolated and characterized (see page 45, including Table 6, of the specification). Second, the hybridization results described at Example 10 on page 70 of the specification demonstrate that the diglycosidases of *Aspergillus oryzae*, *Aspergillus niger*, and *Aspergillus aculeatus* are structurally similar to that of *Aspergillus fumigatus*. Finally, based on the close relationship between microorganisms within the genus *Aspergillus* a person of ordinary skill in the art would have reasonably considered all the diglycosidase enzymes within the scope of the claims to possess the pH, stability, and MW characteristics recited in the claims. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that Applicants were in possession of the claimed invention.

Applicants also note that the claims have been amended to recite polypeptides having “a molecular weight of 47 kDa” rather than “an approximate molecular weight of about 47 kDa.”

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

AMENDMENT UNDER 37 C.F.R. § 1.111  
Appln. No.: 09/806,413

Atty. Docket No. Q63731

**V. Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

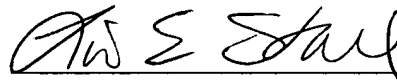
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**23373**

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